REMARKS

Reconsideration is respectfully requested for Claim 7 and 9-17, as amended, said claims having been variously rejected as follows:

Claims 9-17 have been rejected under 35 USC 112, the Examiner alleging in substance that the specification provides no enablement for the use of upregulating agents other than β-1,3 and β-1,6 glucans. However, in view of the present amendment to Claims 7 and 9-17, Claims 7 and 9-17 are believed to fully comply with 35 USC 112.

Claims 7 and 9-17 have been further rejected under 35 USC 103 based upon U.S. Patent Application No. 2002/0150585 to Marciani. This rejection is respectfully traversed.

The Marciani patent application (hereinafter "Marciani") is essentially only a rehash of the prior art openly existing over the past three decades, viz., the use of certain polysaccharides, including β-1,3 glucans, as immunostimulants or adjuvants. This is not a new teaching - there are literally scores of publications showing this concept, even in the list of prior art cited to the USPTO by the present applicants.

However, the prior art, including Marciani, taken individually and collectively, fails to teach, disclose or even suggest that B-1,3 and/or B-1,6 glucans can be used to upregulate the expression of the B7 family of co-stimulatory molecules (e.g. B7.2) on antigen presenting cells (APC's).

The present applicants have discovered, invented and disclosed in the present application, that the expression of the B7 molecules (e.g., B7.2) on APC's is profoundly upregulated by β-1,3-glucans, and the increased numbers of these molecules on the surface of APC's confers upon these important immune cells the ability to provide a necessary second signal to naive T-lymphocytes, thus enabling them to proliferate in response to antigens (e.g., vaccines) and eventually differentiate into effector cells.

Since the T cell is the pivotal cell in both cell-mediated and humoral immunity (e.g., antibody-mediated), methods of activating them have been sought for years. The applicants now provide novel and effective immunopharmacologic methods of upregulating B7 molecules on APC's.

The examiner suggests that the Marciani patent application *"only teaches of the upregulation of B cells"*, and further suggests *"that the processed antigens are expressed on the surface of APC's, which are subsequently shown to stimulate B cells by the processed antigens in order to generate antibodies"* (cited from Marciani columns 1 and 2, paragraph 6).

However, APC's do not stimulate B cells directly, but rather indirectly through "helper" T cells. The discovery by the applicants that β-1,3-glucans upregulate B7 molecule expression on APC's and that these B7 expressing APC's can activate T cells, provides the scientific basis for understanding the way in which most adaptive immune responses, including antibody responses, are regulated.

A careful reading of the Marciani patent application would not lead a skilled artisan to

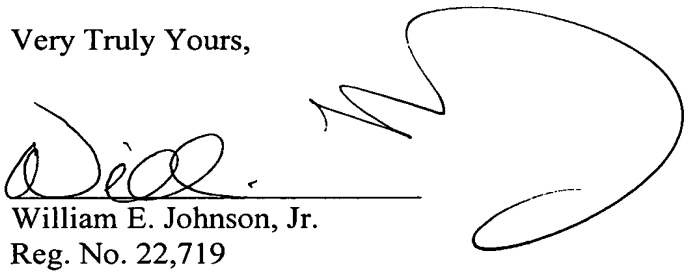
know or even suspect that certain β-1,3-glucan-containing compositions would cause the upregulation of B7 family co-stimulatory molecules. Therefore, the artisan would not be able to attribute the β1,3-glucans the property of stimulating immune responses by this mechanism

Its should be appreciated that Claim 7 has been amended to call for the use of β-1,3 glucans, and newly added Claim 25 calls for the use of β-1,6 glucans.

It is therefore respectfully submitted that Claims 7 and 9-17, as amended, and newly-added Claims 25-37, distinguish over the cited Marciani reference. Accordingly, a favorable reconsideration is respectfully requested for Claims 7 and 9-17, and a favorable consideration is likewise requested for newly-added Claims 25-37.

Should the Examiner, after reviewing the amendments to the claims as set forth herein and the related arguments, remains unconvinced, we would welcome a telephone conference between the Examiner, the undersigned attorney for the applicants, and Dr. Kenneth W. Hunter, one of the inventors of the present application. Dr. Hunter is on the faculty of the Department of Microbiology and Immunology, University of Nevada School of Medicine in Reno, Nevada and has a quite busy schedule, but we can arrange a telephone conference at the convenience of the Examiner. If the Examiner is of the opinion that such a telephone interview is needed and would be appropriate, please call the undersigned attorney for the applicants at 713-355-4200 and the telephone conference will be promptly arranged.

Very Truly Yours,



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